

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 14, 2018



OPTINOSE, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation or Organization)

001-38241

(Commission File No.)

42-1771610

(I.R.S. Employer Identification No.)

1020 Stony Hill Road, Suite 300

Yardley, Pennsylvania 19067

(Address of principal executive offices and zip code)

(267) 364-3500

(Registrant's telephone number, including area code)
(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

- Emerging growth company
- If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 14, 2018, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2018. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

Corporate Presentation

On May 14, 2018, the Company presented an updated Corporate Presentation during its financial results and corporate update call. A copy of the presentation is furnished hereto as Exhibit 99.2 and is incorporated by reference herein.

* * *

The information included in Item 2.02 (including Exhibit 99.1) and Item 7.01 (including Exhibit 99.2) of this Form 8-K, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any Company filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 14, 2018.
99.2	Optinose, Inc. Corporate Presentation dated May 14, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

OptiNose, Inc.

By: /s/ Keith A. Goldan

Keith A. Goldan

Chief Financial Officer

Date: May 14, 2018



**Optinose Reports First Quarter 2018 Financial Results
and Recent Operational Highlights**

Optinose confirms retail pharmacy availability of XHANCE commenced in early April

Company reports more than 1,300 physicians have prescribed XHANCE through the Xperience program

YARDLEY, Pa., May 14, 2018 Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today reported financial results for the quarter ended March 31, 2018, and provided recent operational highlights.

"I am pleased to report that XHANCE is now available in retail pharmacies following our commercial launch in early April," commented CEO Peter Miller. "We have achieved our initial objective with respect to creating brand awareness, we are making good progress with payer coverage, and we are encouraged by the early results for trial and adoption by physicians and the patients they treat. While we are pleased with the progress of our launch to date, we know that long-term success of XHANCE depends on successfully meeting the challenges ahead. Our team is focused on increasing the breadth and depth of prescribers, retaining patients beyond their initial trial phase, increasing the number of patients with "low-hassle" access to XHANCE, and on initiating a clinical program in the fourth quarter of 2018 in pursuit of an additional indication for XHANCE for the treatment of chronic sinusitis."

First Quarter and Recent Highlights

Commercialization of XHANCE™ (fluticasone propionate) nasal spray 93mcg

Brand Awareness

The Company believes that a high level of product awareness will facilitate adoption. Therefore, multiple product awareness initiatives were undertaken in the months following product approval with multi-channel efforts directed at the ENT and allergy specialty audience. Based on our recent market research, aided brand awareness amongst ENT and allergy physicians is 87 percent, which achieves the Company's objective of 85 percent awareness during the launch phase.

Payer Coverage

Recognizing that insurance coverage is important to product acceptance and uptake, the Company has engaged with key pharmacy benefit managers (PBMs) and health plans estimated to represent over 80 percent of U.S. adult commercial lives. Based on currently available third-party data and our internal analyses, the Company believes approximately 74 percent of commercial lives are in a plan in which XHANCE is covered in a Tier 3 formulary position and approximately 61 percent of commercial lives are in a plan that covers XHANCE in a Tier 3 formulary position that is either unrestricted or requires a single step edit. Coverage includes commercial lives represented by two of the three largest PBMs in the U.S. Where permissible, the Company has implemented co-pay assistance and other patient affordability programs to further support patient access.

Sales Force

The Company has engaged approximately 80 sales personnel (through a contract sales organization) who have been trained on XHANCE and have begun interactions with targeted ENT and allergy specialists. These territory managers are deployed primarily in regions where commercial market access is expected to meet or exceed the Company's launch target of 65 percent. The Company anticipates its launch efforts will benefit from active transitions between previously deployed clinical nurse educators and new territory managers. The Company is prepared to flexibly expand the number of territory managers based on market access and experience in the marketplace.

XHANCE Xperience

In March 2018, Optinose introduced an innovative launch program, the XHANCE Xperience program, offering

physicians and their patients an opportunity to gain initial experience with XHANCE. Physicians can enroll eligible patients in this program, and patients will receive up to two XHANCE prescriptions at no cost to them (\$0 co-pay) while physicians will receive feedback on early patient responses to treatment. The Company believes this program will accelerate the ability of physicians to acquire positive patient treatment experiences and therefore improve demand for XHANCE during the early phases of product launch. The program launched on March 5, 2018, and as of May 4, 2018 more than 1,300 unique physicians have prescribed XHANCE and approximately 5,200 units have been dispensed to patients.

Additional Highlights

First Quarter 2018 Financial Results

Revenue

The Company generated \$0.9 million in net revenue through the sales of XHANCE in the three-month period ended March 31, 2018. A large majority of the revenue corresponded with the stocking of the retail distribution channel, with a portion of the revenue related to XHANCE sales through the Xperience program.

Operating expenses and net loss

For the three-month period ended March 31, 2018, research and development expenses were \$1.7 million and selling, general and administrative expenses totaled \$28.0 million. Net loss for the period was \$30.6 million, or \$0.81 per share.

Cash

The Company had cash and cash equivalents of \$209.8 million as of March 31, 2018.

Corporate Guidance

Research and development

In order to support a meeting planned for the next few months, Optinose has submitted questions and key elements of a draft protocol for a planned clinical trial program to the U.S. Food and Drug Administration (FDA). This program is planned in pursuit of the additional indication for XHANCE for "treatment of chronic sinusitis." Pending FDA feedback, the Company expects to initiate the clinical program in the fourth quarter of 2018.

Operating Expenses

The Company believes that total operating expenses (selling, general & administrative expenses and research & development expenses) for 2018 will be in the range of \$119 - \$125 million.

Financial

The Company believes its current cash and cash equivalents are sufficient to fund its operations and debt service obligations through the end of 2019.

Company to Host Conference Call

Members of the Company's leadership team will host a conference call and presentation to discuss financial results and corporate updates beginning at 8:00 a.m. Eastern Time today.

To participate on the conference call, please dial (866) 916-4761 from the U.S. or +1 (409) 216-6496 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until May 21, 2018 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID # 6968158. A simultaneous webcast of the call and presentation can be accessed by visiting the Investors section of Optinose's website at www.optinose.com. In addition, a replay of the webcast will be available on the Company website for 60 days following the event.

OptiNose, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended	
	March 31,	
	2018	2017
Net product revenues	\$ 865	\$ —
Cost of product sales	200	—
Gross margin	665	—
Operating expenses:		
Research and development	1,701	4,230
Selling, general and administrative	28,011	3,073
Total operating expenses	29,712	7,303
Loss from operations	(29,047)	(7,303)
Other expense	1,525	772
Net loss	\$ (30,572)	\$ (8,075)
Deemed dividend	—	3,067
Accretion to redemption value	—	528
Net loss attributable to common stockholders	\$ (30,572)	\$ (11,670)
Net loss per share of common stock		
basic	\$ (0.81)	\$ (2.87)
diluted	\$ (0.81)	\$ (2.87)
Weighted average common shares outstanding		
basic	37,849,199	4,067,717
diluted	37,849,199	4,067,717

OptiNose, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31,	December 31,
	2018	2017
	(Unaudited)	
Cash and cash equivalents	\$ 209,771	\$ 234,854
Other assets	10,791	6,282
Total assets	\$ 220,562	\$ 241,136
Total current liabilities	\$ 22,488	\$ 14,777
Long-term debt, net	71,963	71,863
Total stockholders' equity	126,111	154,496
Total liabilities and stockholders' equity	\$ 220,562	\$ 241,136

About Optinose

Optinose is a global specialty pharmaceutical company focused on serving the needs of patients cared for by ear, nose and throat (ENT) and allergy specialists. Optinose has offices in the U.S., the U.K. and Norway. To learn more, please visit www.optinose.com or follow us on Twitter and LinkedIn.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to the initiation and timing of a clinical program of XHANCE for chronic sinusitis; projected Company operating expenses for 2018; the adequacy of the Company's current cash and cash equivalents to fund operations and debt service obligations through the end of 2019; the potential benefits of XHANCE and the Xperience Program; and other statements regarding the Company's future operations, financial performance, financial position, prospects, objectives and other future events. Forward-looking statements are based upon management's current expectations and assumptions and are subject to a number of risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated by such forward-looking statements including, among others: the Company's ability to successfully commercialize XHANCE; physician and patient acceptance of XHANCE; the Company's ability to obtain adequate third-party reimbursement for XHANCE (market access); our ability to successfully commercialize XHANCE without the support provided by the Xperience program; market opportunities for XHANCE may be smaller than expected; uncertainties and delays relating to the initiation, enrollment and completion of clinical trials; unanticipated costs; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" and elsewhere in our most recent Form 10-K and Form 10-Q filings with the Securities and Exchange Commission - which are available at www.sec.gov. As a result, you are cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statements made in this press release speak only as of the date of this press release, and we undertake no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

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**Building a Leading ENT / Allergy
Specialty Company**

First Quarter 2018 Update

May 14, 2018

Forward Looking Statements

This presentation and our accompanying remarks contain “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to: potential benefits of XHANCE™ and the Xperience program; market access objectives; market opportunities; commercial strategies; the initiation and timing of clinical trials for chronic sinusitis; and other statements regarding our future operations, financial performance, prospects, intentions, objectives and other future events.

Forward-looking statements are based upon management’s current expectations and assumptions and are subject to a number of risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated by such forward-looking statements including, among others: physician and patient acceptance of XHANCE; our ability to obtain adequate third-party reimbursement for XHANCE (market access); our ability to successfully commercialize XHANCE without the support provided by the Xperience program; uncertainties and delays relating to the initiation, completion and results of clinical trials; market opportunities for XHANCE may be smaller than we believe; and the risks, uncertainties and other factors discussed in the “Risk Factors” section and elsewhere in our most recent Form 10-K and Form 10-Q filings with the Securities and Exchange Commission – which are available at <http://www.sec.gov>. As a result, you are cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statements made in this presentation speak only as of the date of this presentation, and we undertake no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

This presentation and our accompanying remarks also contain estimates, projections, market research and other data concerning our industry, markets for certain diseases and XHANCE. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events and circumstances may differ materially from events and circumstances reflected in this information. You are cautioned not to give undue weight to such information.

Recent Key Accomplishments

87%

Aided Awareness within ENT / Allergy Specialty*

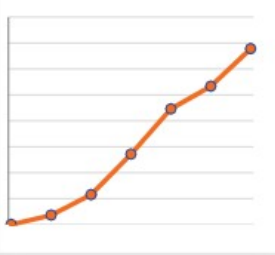


Retail Launch April 2, 2018

74%

Commercial Lives Covered (61% Tier 3 Single Step or better)*

Total Trialists



Encouraging Physician Adoption in ENT / Allergy



Submitted CS trial design to FDA

Continued to Build Capabilities to Support a Commercial Stage Company

Our Research on Over 300 Products Suggests Successful Launches are Driven by Four Key Factors



Attractive Market...with High Unmet Need



Importantly Differentiated Product



Awareness / Execution



Market Access



CRS is an Attractive Market...With High Unmet Need

30 Million

US Adults suffer from CRS and up to 10 million of them have nasal polyps

9.75 Million

CRS patients seek physician care annually

3.5 Million

CRS patients treated by ENT/Allergy specialists

1.2 Million

NP patients treated by ENT/Allergy specialists

High Burden

- Disease persists for many years
- Significant quality of life impact (comparable to CHF, COPD, Angina)

Recognized Unmet Need

- **80% of patients** are frustrated with lack of symptom relief with prior intranasal steroids (INS)
- **75% of physicians** believe INS nasal sprays do not work well because they do not sufficiently reach site of inflammation

Source: Palmer J et al . A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society; September 16-17, 2016; San Diego, CA
Optinose Market Research. Data on file.

optinose



Perceived Differentiation of XHANCE on Key Choice Drivers Translates into High Intention to Prescribe

XHANCE is Perceived as Differentiated on Key Choice Drivers

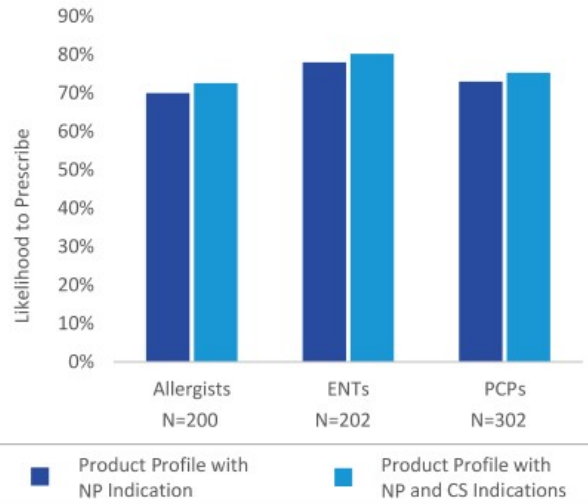
- Improvement in nasal blockage / congestion as early as week 4
- Elimination of polyps at week 24
- Improvement in sense of smell / taste
- Overall Patient Satisfaction

N=200 (100 ENTs and 100 Allergists)



Physician Stated Interest to Prescribe*

High Physician Interest in Prescribing is Reported After Presenting Product Profile (With Only Nasal Polyp Indication)

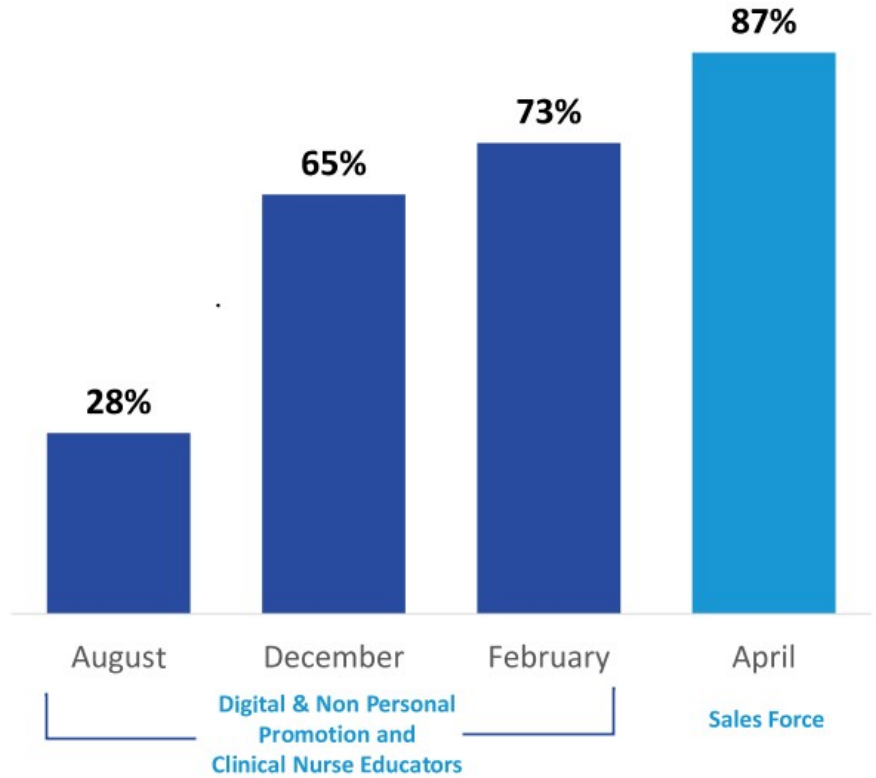




Multi-Channel Integrated Marketing Program Increased Aided Awareness to 87%

Awareness & Execution

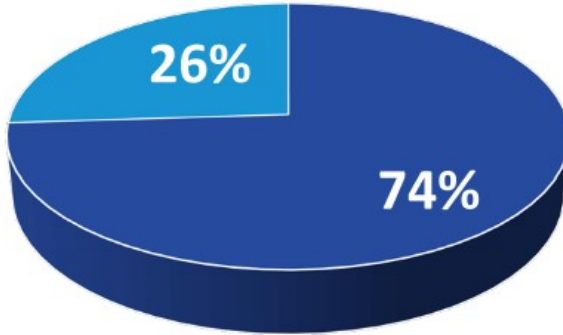
- Digital and Non-Personal Awareness campaign implemented 9/17/2017
- Clinical Nurse Educators deployed 11/18/2017
- Xhance Xperience program introduced in early March
- Approximately **80** Territory Managers deployed on March 5th
- TMs have reached **54%** of target Physicians with an average frequency of **3.1** as of May 4







XHANCE has Good Early Launch Market Access

XHANCE Overall
Access: April 2018



Access Key

-  NDC Blocked / Not Covered
-  Covered (Single step edit, double step edit, PA or better)

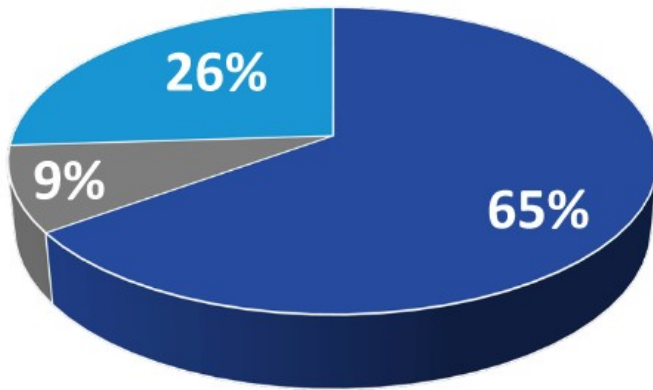
Source: Third party syndicated data and internal analyses

- Nationally, we believe **74% of commercial lives** are in a plan where XHANCE is covered.
- We believe new drugs that launch at approval typically have only **40% of commercial lives covered** and **60% of commercial lives blocked or not covered**.
- XHANCE is available to patients through multiple payers that normally place new-to-market restrictions on access.






XHANCE National Market Access

XHANCE Overall Access: April 2018



Access Key

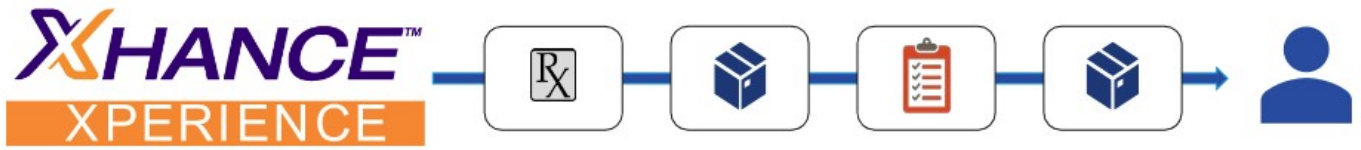
-  NDC Blocked / Not Covered
-  Covered (Double step edit or PA to indication)
-  Covered (Unrestricted, Single step edit, or PA to Prior INS)

Source: Third party syndicated data and internal analyses

- We are focused on creating access for patients that minimizes hassle for prescribers and patients.
- XHANCE is on formulary for **65% of commercial lives** in a Tier 3 position requiring a previous trial of an INS or better.
- Our goal is for **75% of commercial lives** to have “limited hassle” access to XHANCE by the end of 2018.



XHANCE Xperience Program - Initiated in Market on March 5th

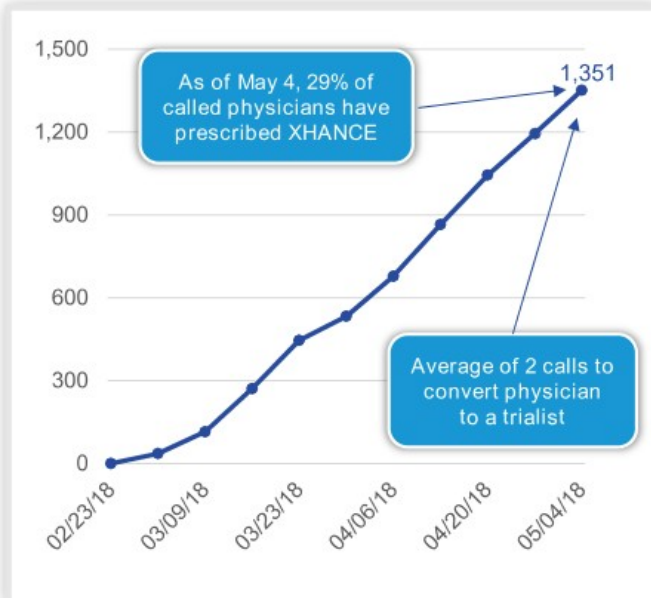


- Innovative launch program, planned for March through June, offering physicians and patients an opportunity to gain initial experience with XHANCE
- Designed to facilitate accelerated trial and adoption, and to help address “practice inertia”
- Eligible patients receive up to two prescription fills of XHANCE at no cost to them (\$0 co-pay)
- Patients required to complete survey for second prescription fill
- A mail-order pharmacy coordinates fulfillment

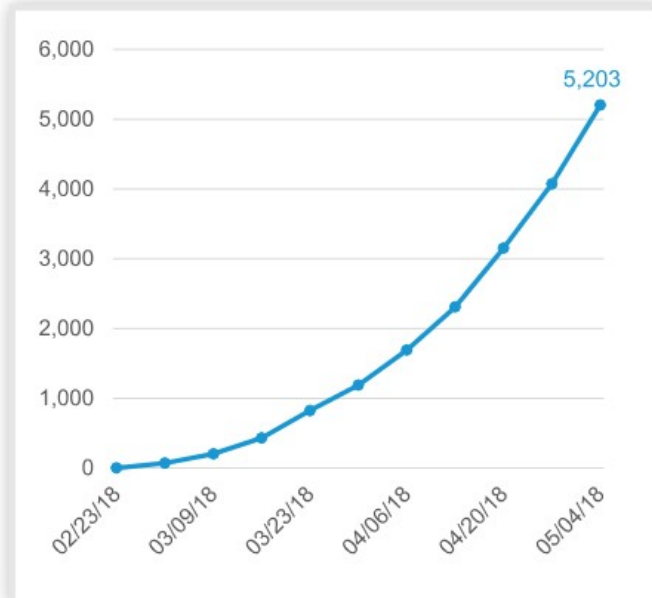


XHANCE Launch Accelerated by Xperience

Cumulative Physician Trialists



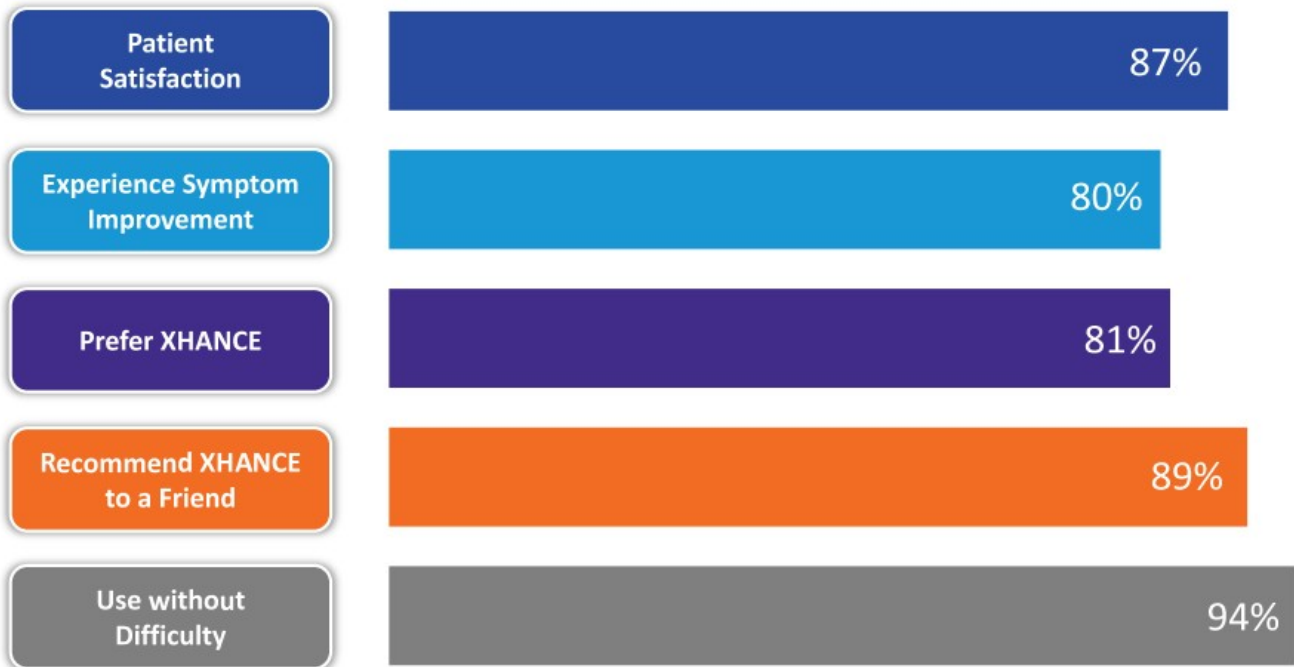
Cumulative Units Dispensed





Encouraging Feedback From Xperience Program Survey

Patient Responses Prior to Month 2 Refill (N=321)



Note: in the same period that the 321 responses were received, 50 patients declined the opportunity to respond to the survey.

Market Dynamics, Product Characteristics and Execution to Date Provide a Strong Foundation for a Successful Launch



Indicator/Objective Assessment



Attractive Market...with High Unmet Need

Current Patients Dissatisfied with Existing Treatment



>80%

>80% of patients frustrated with lack of symptom relief with their current INS



Physician Dissatisfaction with Current Treatments



>75%

>75% of physicians agree, in part, that INS medications do not work because they do not reach the site of inflammation



Differentiated Product

Physician Stated Interest to Prescribe

70%–80%

Physicians' stated interest to prescribe based on product profile similar to XHANCE



Awareness / Execution

Awareness During Launch



87%

Aided awareness within ENTs and allergists during launch



Market Access

Covered Commercial Lives at Launch

65%

Tier 3 coverage at launch
(Currently at 74% T3 coverage;
61% T3 unrestricted or single-step)



Financial Review

Q1 2018 Revenues and Average Selling Price (ASP)

- A large majority of Q1 revenue is related to inventory shipped in late-March to support retail pharmacy availability of XHANCE in April.
- In accordance with GAAP accounting rules, we estimated ASP for XHANCE, with specific assumptions for units sold into the retail channel as well as units sold through the Xperience program.
- The ASP for the Xperience program is significantly less than the ASP for the retail channel.

Q2 and Full Year 2018 Perspectives

- As planned, we expect the Xperience program to be the primary source of demand for XHANCE in Q2.
- We believe the Xperience program will help accelerate demand in the early phase of launch.
- As a result of this program, we expect ASP and Gross Margin percentage in Q2 to be significantly less than in Q1.
- We are focused on maximizing patient retention following the Xperience program.

Chronic Sinusitis Supplemental Indication (sNDA)

CS study design submitted to FDA, meeting requested

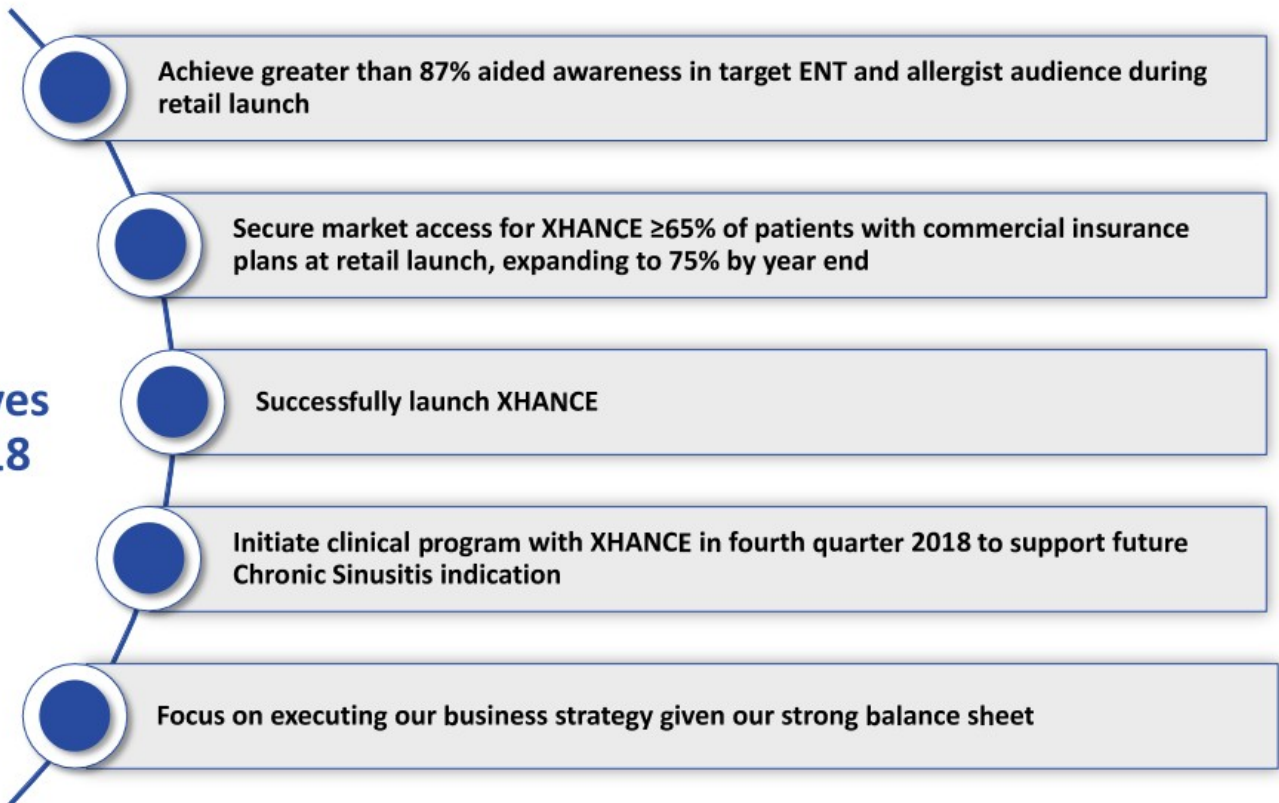
Selection of CRO and study locations

First patients expected to enroll in 4Q 2018

Chronic Sinusitis trial design expected to include co-primary endpoints: both an objective measure of inflammation and a subjective measure of symptom relief

2018 Stands to be an Important Year

Key Objectives For 2018



Investor Relations – NASDAQ: OPTN

Analyst Coverage¹

BMO: Gary Nachman

Jefferies: David Steinberg

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 31 March 2018:

- \$210 million in cash
- 37.9 million common shares o/s
- 8.2 million options & warrants o/s
- Long-term debt: \$75 million

Optinose Investor Contact

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[@optinose](https://twitter.com/optinose)

1 - Optinose is followed by the analysts listed above. Please note that any opinions, estimates or forecasts regarding the Company's performance made by these analysts are theirs alone and do not represent opinions, forecasts or predictions of Optinose or its management. Optinose does not by its reference above or distribution imply its endorsement of or concurrence with such information, conclusions or recommendations.



**Building a Leading ENT / Allergy
Specialty Company**

First Quarter 2018 Update

May 14, 2018
